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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER

NASSER, R

ART UNIT

PAPER NUMBER

3311

DATE MAILED:

04/01/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

490503

Applicant(s)

Nassen

Examiner

Quinn et al

Group Art Unit

3311

☒ Responsive to communication(s) filed on 2/4/97☐ This action is FINAL.☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 45-64 is/are pending in the application.

Of the above, claim(s) is/are withdrawn from consideration.

☐ Claim(s) is/are allowed.☒ Claim(s) 45-64 is/are rejected.☐ Claim(s) is/are objected to.☐ Claims are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.☐ The drawing(s) filed on is/are objected to by the Examiner.☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.☐ The specification is objected to by the Examiner.☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been☐ received.☐ received in Application No. (Series Code/Serial Number)☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received:

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 18125☐ Interview Summary, PTO-413☐ Notice of Draftsperson's Patent Drawing Review, PTO-948☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

The examiner acknowledges applicant's request under 37 C.F.R. § 1.607 to provoke an interference with U.S. patent number 5,435,308 to Gallup et al. However, as none of the present claims are allowable, the interference is not being set up.

The examiner further notes that the old PTO form 892's submitted by applicant and the international search reports have been considered. However, the examiner notes a great deal of overlap in the forms submitted by applicant and requests that applicant review the forms, consolidate the references, eliminating redundancies.

The drawings are objected to under 37 C.F.R. § 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the heating filament printed on two sides of a substrate must be shown or the feature cancelled from the claim. No new matter should be entered.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification, as originally filed, fails to provide support for the invention, as now claimed. With

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respect to claim 55, applicant has recited that the filament is printed on two sides of a substrate. The examiner notes that on page 19, line 12, applicant recites that the filament is printed in the middle of a substrate. Therefore, the claim language contradicts the specification and introduces new matter.

Claim 55 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 45-54 and 56-64 are rejected under 35 U.S.C. § 103 as being unpatentable over Willis et al in view of Khalil '910. Willis et al shows all of the features of the claims except that it measures cardiac output using a cold bolus injection. The examiner notes that Willis et al shows the port P' on a "necked

down" portion of the catheter. The examiner further notes that the portion 105 of the catheter necks down to portion 101. Hence, portion 101 is the necked down portion. Khalil teaches that cold bolus injections and using external heaters heat the blood are equivalent methods of measuring cardiac output (see background section). Accordingly, it would have been obvious to modify Willis et al to use a heating coil, rather than a cold bolus injection, as it is merely the substitution of one known equivalent measurement technique for another. Claim 46 is rejected for the reasons given above. Claim 47 is rejected in that the necked down portion includes a portion of the catheter that is 14-15 centimeters from the distal end of the device. Claim 48 is rejected in that the heater is a coil wrapped about the necked down portion. Claim 49 is rejected in that there is a thermistor distal to the heater in the combination. Claims 50-52 are rejected in that the coil of the combination has center to center spacings such that adjacent turns do not contact each other, has an outer sheath and the diameter of the coil approximates that of the catheter when wrapped about the catheter. Claim 53 is rejected in that the port P/M' is distal to the interface. Claim 54 is rejected in that the exact distance between the end of the catheter and the heater varies with catheter size and would have been obvious to one skilled in the art. Claims 56-58 and 61-63 are rejected in that the

combination shows all of the features of the claims. With respect to claim 57, the examiner notes that Willis has two ports, P/M' and T/F'. With respect to claim 61, the examiner notes that the location of the wiring and optical fibers is not for any particular purpose, nor does it solve any stated problem. Accordingly, it would have been a matter of design choice on how to configure the wiring, as all configurations appear to be equivalent. See In re Kuhle, 526 F.2d 553 (CCPA 1975). Claim 59 and 60 are rejected in that there is a fluid injectate lumen and port P/M' for injecting a fluid into the blood, that is distal to the interface. Claim 64 is rejected for the reasons given above. In addition, the examiner notes that the location of the ports of the combination will be substantially that recited in the claims.

Claim 55 is rejected under 35 U.S.C. § 103 as being unpatentable over Willis et al in view of Khalil as applied to claims 45-54, 56-58, and 61-63 above, and further in view of Grise. Grise teaches that a substrate based heater is an improvement over a single wire of Khalil, in that the cost is much less and the heaters are more flexible in use. Accordingly, it would have been obvious to modify the above combination to use the substrate based heater of Grise, for the reasons given above.

Applicant's arguments filed February 4, 1997 have been fully considered but they are not deemed to be persuasive.

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Applicant has asserted that the examiner's reasoning concerning the denial of the request to set up an interference is illogical. It is the examiner's position that applicant has no claims that are presently allowable. Hence, no interference can be set up, by definition. The examiner sees nothing illogical in this.

Applicant's amendments to claims 45, 57, 58, 61, and new claim 64 have been addressed above.

Applicant has asserted that Grise et al does not teach an external filament of that the filament can be incorporated into a cardiac catheter. It is the examiner's position that this argument is irrevelant to prosecution. There is no requirement that there be an explicit suggestion to combine the references. rather, there need only be some suggestion, obtain after viewing he references as a whole. Here, Grise relates to problems in single wire heating filaments. The reference, Khalil, uses a single wire heating filament. Hence, the references, when viewed as a whole, provide motivation to make the combination.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Nasser whose telephone number is (703) 308-3251 or to Jennifer Bahr Supervisory Patent Examiner for Art Unit 3311, at (703) 308-1066.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858. In addition, the Group Fax number is (703) 305-3590.

Robert S. Nasser J.

**ROBERT NASSER
PATENT EXAMINER
GROUP 3300**

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RLN
March 28, 1997